Remarks

Claims 20-38 are pending in the subject application. By this Amendment, Applicants have canceled claims 21, 22, 29, and 36 and amended claims 20, 28, and 35. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Applicants respectfully submit that the amendments presented herein, wherein elements of dependent claims have been incorporated into the independent claims, will require no further search or examination on the part of the Examiner and do not constitute new matter. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 20, 23-28, 30-35, 37, and 38 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 20-38 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject application and as lacking sufficient written description. The Examiner acknowledges that the claimed methods are enabled for use of interferons and interferon chimeras, but asserts that the specification does not enable or provide adequate written description for methods using biologically active fragments of these molecules.

Applicants respectfully assert that there is adequate written description and enablement of biologically active fragments of interferon and interferon chimeras. However, by this Amendment, Applicants have deleted "biologically active fragments" language from the claims. Thus, the rejection of the claims under 35 USC §112, first paragraph, is now moot. In accordance with the Doctrine of Equivalents and accepted principles of claim construction, Applicants intend that the claims as amended encompass interferon tau proteins having various additions, deletions, and substitutions of amino acids in the sequence of the protein as long as those proteins exhibit substantially the same activity as interferon tau protein. It should be understood that these amendments have been made solely to expedite prosecution of the subject application to completion and should not be construed as narrowing the scope of equivalents to which the claims will be entitled under the Doctrine of Equivalents. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, first paragraph, is respectfully requested.

Claims 20-38 are rejected under 35 USC §112, second paragraph, as indefinite. The Examiner asserts that "it remains unclear why and when allergen-specific IgE production needs to be

suppressed or inhibited." Similarly, the Examiner asserts that, in regard to claim 28, "it is unclear . . . why or when one would want to suppress or inhibit proliferation of an IgE-producing cell." Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the Examiner's statements under this rejection in the instant Office Action do not clarify the Examiner's grounds for rejection of the claims as indefinite. Applicants again note that claims 20, 28, and 35 do not recite an "IgE-related condition."

In any event, Applicants respectfully maintain that the claims are clear and are not indefinite. An ordinarily skilled artisan understands the metes and bounds of the claims. The Examiner has not explained in the Office Action why the claim language would be unclear or indefinite to an ordinarily skilled artisan. Applicants respectfully assert that it would be clear to an ordinarily skilled artisan, for example, a clinician, why and when allergen-specific IgE production should be treated to be suppressed or inhibited. For example, an ordinarily skilled clinician can evaluate a patient as to allergen-specific IgE production and determine if it is too high and if it should be treated to suppress or inhibit the IgE production. This is what clinicians do - - they evaluate the disease condition, the symptoms, *etc.* and make a diagnosis and prescribe an appropriate treatment. Clinicians are trained to provide this service. Applicants also respectfully assert that it would be clear to an ordinarily skilled artisan why and when one would want to suppress or inhibit proliferation of an IgE-producing cell. For example, suppression or inhibition may be desirable when IgE-producing cells are proliferating during an allergic response to an allergen. In view of the above remarks, Applicants respectfully assert that the claims are not indefinite. Reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 20 and 22-38 are rejected under 35 USC §§102(a) and 102(e) as anticipated by Soos *et al.* (U.S. Patent No. 5,906,816). The Examiner asserts that the Soos *et al.* patent teaches mammalian interferon tau and its use in the treatment of autoimmune disease. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully maintain that the '816 patent does not anticipate the claimed invention. In making this rejection, the Examiner makes a broad and sweeping statement without providing any evidence to support it. Specifically, the Examiner asserts that the persons described in the '816 patent "would include a population suffering from IgE-related allergy . . .." The Examiner

has not provided any basis for this statement. Moreover, even if one accepts, *arguendo,* that the Examiner's statement is true, this does not result in anticipation of the claimed invention by the '816 patent. As Applicants pointed out in the Amendment dated November 28, 2005, in order for the '816 patent to anticipate the claimed invention it must have been recognized by an ordinarily skilled artisan that the interferon tau composition described in the '816 patent inhibited allergen-specific IgE production or inhibited proliferation of IgE-producing cells. The Examiner has provided no evidence that an ordinarily skilled artisan would have recognized from the disclosure in the '816 patent that such inhibition occurred. The Examiner has cited court decisions for the proposition that "recognition" is not required (see *Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ 2d 1664 (Fed. Cir. 2003) and *Toro Co. v. Deere & Co.*, 69 USPQ 2d 1584 (Fed. Cir. 2004)). Applicants respectfully assert that the subject invention is distinguishable over the cited cases. The *Schering* case dealt with claims to a composition of matter whereas the Applicants' claimed invention is directed to method of use claims. Applicants also respectfully assert that patent law still requires recognition by a skilled artisan of inherent properties and elements in a prior art reference. U.S. patent law is still governed by the decisions of the U.S. Supreme Court in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923) and *Tilghman v. Proctor*, 102 U.S. 707 (1880). These cases cannot be overruled by decisions of lower federal courts such as the Court of Appeals for the Federal Circuit. In the *Tilghman* decision, the Supreme Court ruled that anticipation could not be found where the prior art process was not directed to the process claims at issue and because the product produced by the method was accidentally and unwittingly produced, without knowledge of what was done or how it was done. In *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), the Supreme Court held that unintentional and unappreciated results of a prior art method did not constitute anticipation. The *Schering* panel sought to distinguish the facts of that case over the *Eibel* and *Tilghman* decisions. However, as noted above, lower courts cannot overrule U.S. Supreme Court decisions and, therefore, *Eibel* and *Tilghman* remain the law to be applied. Moreover, the *Schering* and *Toro* decisions are simply opinions of but a single panel of judges of the Court of Appeals for the Federal Circuit (CAFC); they are not *en banc* decisions. Therefore, other cases of the CAFC are still good law and have not been overruled by *Schering* or *Toro*. For example, one panel of CAFC judges, in the case *Crown Operations International Ltd. v. Solutia Inc.*,

62 USPQ 2d 1917 (Fed. Cir. 2002), held that if a limitation or element is to be considered to be inherently disclosed in a prior art reference, then the limitation or element "must be necessarily present and a person of ordinary skill in the art would recognize its presence." (citing *In re Robertson*, 49 USPQ 2d 1949 (Fed. Cir. 1999) and *Continental Can Co. USA, Inc. v. Monsanto Co.*, 20 USPQ 2d 1746 (Fed. Cir. 1991). Thus, the CAFC in the *Crown Operations* case indicated that recognition by an ordinarily skilled artisan is an element of inherency. A single panel decision of the CAFC cannot overrule earlier caselaw established by the CAFC and its predecessor court, the Court of Customs and Patent Appeals. A change in law can only be effected by an *en banc* decision by the CAFC, something which has not yet occurred. Thus, Applicants respectfully assert that the *Eibel*, *Tilghman, Crown Operations,* and *Continental Can Co. USA* are still good law and are applicable to the subject application.

The Examiner also states in the Action that "A compound and all of its properties are inseparable; they are one and the same thing and simply stating a new property of interferon tau does not render the claimed method of inhibiting angiogenesis of the instant application free of the art" (and citing *In re Papesch*; *In re Swinehart*; and *In re May*) (emphasis added). As an initial point of clarification, Applicants are not claiming a method of inhibiting angiogenesis; the claims in the subject application are directed to methods for inhibiting allergen-specific IgE production and proliferation of IgE-producing cells. Next, and contrary to the Examiner's assertion, Applicants respectfully assert that their claimed methods are not "simply stating a new property of interferon tau." The claims, as indicated above, are directed to inhibiting allergen-specific IgE production and inhibiting proliferation of IgE-producing cells by administering an effective amount of interferon tau to a person or animal in need of suppression or inhibition of allergen-specific IgE production or proliferation of IgE-producing cells. Thus, the claimed methods require identification of a person in need of treatment for the recited condition. The claimed methods of the subject application do not merely recite a use of a property of interferon tau. Moreover, the '816 patent does not teach or suggest identifying a person or animal in need of inhibiting allergen-specific IgE production or proliferation of IgE-producing cells. Lastly, the claimed invention of the subject application is distinguishable over the court decisions cited by the Examiner in the Office Action. The *In re Papesch* and *In re Swinehart* cases dealt with patentability of claims directed to compositions of

matter, with the decisions simply confirming that discovery of a new property of an old composition does not impart patentability to claims directed to the composition. The claims in the subject application are directed to methods of use, not compositions of matter. Applicants are not claiming an old composition based on discovery of a new property. Thus, the *In re Papesch* and *In re Swinehart* decisions are inapplicable to Applicants' claimed invention. The *In re May* case pertains to patentability of claims directed to a method of effecting analgesia using a known composition. However, in *In re May*, the prior art explicitly disclosed methods for effecting analgesia using the known composition, which was exactly what the applicants were claiming except that the applicants' method claim also included the element of not "producing physical dependence." In contrast, Applicants of the subject application are not claiming a method of use that is identical to that disclosed in the '816 patent but with the addition of some additional property associated with interferon tau. For example, the claims in the subject application require identification of a person or animal in need of inhibition of allergen-specific IgE production or inhibition of proliferation of IgE-producing cells. Thus, the claims in the subject application are novel and distinct from the methods disclosed in the '816 patent. As the Examiner acknowledges in the instant Office Action at page 8, lines 7-8, "the '816 patent does not teach the suppression or inhibiting allergen-specific IgE production by administering interferon tau . . ." (emphasis added). Thus, the claimed invention is also distinguishable from the facts of *In re May*.

Applicants note that claim 20 has been amended herein to incorporate the elements of dependent claim 21. Dependent claim 21 was not included in the §102 rejections over the '816 patent. Thus, the rejection of claim 20, and claims dependent therefrom, is moot and these claims should not be rejected over the '816 patent. If the Examiner subsequently asserts that claim 21 was also anticipated by the '816 patent, then this would constitute a new ground of rejection (and one not necessitated by Applicants' amendments) and the next Office Action from the Patent Office could not properly make a final rejection of the claims.

In view of the above, reconsideration and withdrawal of the rejections under 35 USC §§102(a) and 102(e) is respectfully requested.

Claims 20, 21, 27, 28, 34, and 35 are rejected under 35 USC §102(b) as anticipated by Mujtaba *et al.* (1998). The Examiner indicates that the Mujtaba *et al.* reference describes the

inhibition of MBP-induced proliferation of B cells from experimental allergic encephalitis (EAE) mice following treatment with interferon tau. The Examiner asserts that such use would inherently result in the suppression of IgE production and thereby anticipates the invention. Applicants respectfully traverse this ground of rejection.

Applicants respectfully maintain that the Mujtaba *et al.* reference does not teach or suggest Applicants' claimed invention. As noted in the Amendment dated November 28, 2005, the Mujtaba *et al.* reference is directed to work using mice that have experimental allergic encephalitis (EAE). Applicants respectfully maintain that there is **no relation** between EAE and allergen-specific IgE production or proliferation of IgE-producing cells. EAE is a model for an autoimmune disorder, not for an allergic disorder. There is no teaching or suggestion in the Mujtaba *et. al.* reference that the mice also had a disorder involving allergen-specific IgE production or proliferation of IgE-producing cells. A person of ordinary skill in the art would not look to publications pertaining to the EAE model in order to identify an animal in need of suppression or inhibition of allergen-specific IgE production or for teachings pertaining to suppression or inhibition of allergen-specific IgE production. Thus, the cited reference does not teach or suggest identifying a person or animal in need of suppression or inhibition of allergen-specific IgE production, nor does it teach or suggest administering an effective amount of interferon tau to the identified person or animal.

However, by this Amendment, Applicants have amended independent claims 20, 28, and 35 to include the elements of dependent claims 22, 29, and 36, respectively. Claims 22, 29, and 36 were not included in the §102 rejection over the Mujtaba *et al.* reference. Thus, the rejection of the claims over the Mujtaba *et al.* reference is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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